Safety Assessment of Polysilicone-11
as Used in Cosmetics

Status: Draft Tentative Report for Panel Review
Release Date: August 21, 2020
Panel Meeting Date: September 14 – 15, 2020

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Lisa A. Peterson, Ph.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Priya Cherian, Scientific Analyst/Writer, CIR.
Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Priya Cherian, Scientific Analyst/Writer, CIR
Date: August 21, 2020
Subject: Safety Assessment of Polysilicone-11 as Used in Cosmetics

Enclosed is the Draft Tentative Report on the Safety Assessment of Polysilicone-11 as Used in Cosmetics (polysi092020rep). At the December 2019 meeting, the Panel issued an insufficient data announcement (IDA) for this ingredient. In order to determine the safety of this ingredient, the following data were requested:

- residual monomers and other reactants (e.g., polymerization initiators, chain propagators, terminators, solvents),
- molecular weight distribution
- composition
- impurities
- 28-day dermal toxicity
- mammalian genotoxicity
- sensitization/irritation data at maximum use concentration.

Since the issuing of the IDA, the following unpublished data have been received, highlighted throughout the report, and included in this packet:

- Updated method of manufacturing and impurities information (polysi092020data1)
- Data on a cytotoxicity assay on a trade name mixture containing 12 – 16% Polysilicone-11, 43 – 50% dimethicone, and 36 – 42% cyclopentasiloxane (polysi092020data1)
- Summary HRIPT data on a trade name mixture containing 98% Polysilicone-11 and 2% laureth-12 (polysi092020data2)

Also included in this packet are updated 2020 VCRP data (polysi092020FDA) and corrected concentration of use data (polysi092020data3). Polysilicone-11 is now reported to be used in 440 total formulations (it was previously reported to be used in 420 total formulations). Corrected concentration of use data indicate that the maximum concentration of use reported for Polysilicone-11 is 19.9% in other skin care preparations. The previous maximum concentration of use was reported to be 35% in face and neck preparations; the current maximum concentration of use for this category is reported to be 14.6%.

Other documents included in this package for your review are the CIR report history (polysi092020hist), flow chart (polysi092020flow), literature search strategy (polysi092020strat), ingredient data profile (polysi092020prof), minutes from the December 2019 meeting (polysi092020min), and addressed comments from Council on the Draft Report (polysi092020pcpc).

After reviewing these documents, if the available data are deemed sufficient to make a determination of safety, the Panel should issue a Tentative Report with a safe as used, safe with qualifications, or unsafe conclusion, and Discussion items should be identified. If the available data are insufficient, the Panel should issue a Tentative Report with an insufficient data conclusion.
SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY  Polysilicone-11

MEETING  September 2020

<table>
<thead>
<tr>
<th>Public Comment</th>
<th>CIR</th>
<th>Expert Panel</th>
<th>Report Status</th>
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<tr>
<td>Priority List INGREDIENT</td>
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<td>PRIORITY LIST</td>
<td></td>
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<tr>
<td>Notice to Proceed without an SLR July 2, 2019</td>
<td>Draft Report</td>
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<td>IDA Notice Dec 13, 2019</td>
<td>Draft TR</td>
<td>IDA</td>
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<td>IDA</td>
<td></td>
<td>DRAFT TENTATIVE REPORT Sept 2020</td>
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<td>Draft FR</td>
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<td>Issue TR</td>
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<td>PUBLISH</td>
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<td>Different Conclusion</td>
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</table>
Polysilicone-11 History

July 2019

-A notice to proceed (NTP) was issued and the following data was requested:

- Chemistry information, including composition and structure, method of manufacture, and impurity data
- Toxicokinetics data relevant to routes of exposure expected with cosmetic use
- General toxicity data
- Developmental and reproductive toxicity data
- Genotoxicity data
- Carcinogenicity data
- Dermal irritation and sensitization data
- Inhalation toxicity data
- Any other relevant safety information that may be available

-The following unpublished data was received:

- HRIPTs on a leave-on product containing 9.675% Polysilicone-11 and a rinse-off product containing 19.830% Polysilicone-11 was received
- Summary toxicity information received on various mixtures containing Polysilicone-11
- An in vitro tissue equivalent assay to evaluate the ocular irritation potential of a face cream containing 1.6% Polysilicone-11
- A human cumulative irritation patch test on a face cream containing 1.6% Polysilicone-11

August 2019

-The following unpublished data was received:

- General method of manufacturing information
- A 48-hour patch test performed using a lipstick containing 1.8% Polysilicone-11
- A MatTek EpiOcular™ methyl thiazole tetrazolium (MTT) Viability Assay on a test substance containing 98.5% Polysilicone-11
- A human dermal maximization assay performed to evaluate the contact-sensitization potential of a liquid blend containing 24.625% Polysilicone-11
- An HRIPT on a product containing 1.45% Polysilicone-11

December 2019

-Panel reviews the draft report and issues an IDA
-Insufficiencies include:
  - residual monomers and other reactants (e.g., polymerization initiators, chain propagators, terminators solvents),
  - molecular weight distribution
  - composition
  - impurities
  - 28-day dermal toxicity
  - mammalian genotoxicity
  - sensitization/irritation data at maximum use concentration.

Data received from Council:

- impurities/method of manufacturing data received
- data on a cytotoxicity assay on a trade name mixture containing 12 – 16% Polysilicone-11, 43 – 50% dimethicone, and 36 – 42% cyclopentasiloxane

-Council Comments on the Draft Report received

corrected information on concentration of use received (maximum concentration decreased to 19.9%)

**March 2020**

- HRIPT on a trade name mixture containing 98% Polysilicone-11 and 2% laureth-12 received

**September 2020**

-Draft Tentative Report reviewed by Expert Panel
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<th>Impurities</th>
<th>Toxicokinetics</th>
<th>Acute Tox</th>
<th>Repeated Dose Tox</th>
<th>DART</th>
<th>Genotox</th>
<th>Carci</th>
<th>Dermal Irritation</th>
<th>Dermal Sensitization</th>
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* “X” indicates that data were available in a category for the ingredient
### Polysilicone-11

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#### Search Strategy

*document search strategy used for SciFinder, PubMed, and Toxnet*

#### Typical Search Terms

- INCI name
- CAS numbers
- chemical/technical names

**Key Words:** dermal, irritation, sensitization, inhalation, metabolism, toxicity
Typical Search Terms

- INCI names
- CAS numbers
- chemical/technical names
- additional terms will be used as appropriate

Search Engines

  (includes Toxline; HSDB; ChemIDPlus; DART; IRIS; CCRIS; CPDB; GENE-TOX)
- Scifinder: [https://scifinder.cas.org/scifinder](https://scifinder.cas.org/scifinder)

Appropriate qualifiers are used as necessary

Search results are reviewed to identify relevant documents

Pertinent Websites

- wINCI: [http://webdictionary.personalcarecouncil.org](http://webdictionary.personalcarecouncil.org)
- FDA databases: [http://www.ecfr.gov/cgi-bin/ECFR?page=browse](http://www.ecfr.gov/cgi-bin/ECFR?page=browse)
- FDA search databases: [http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm](http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm);
- GRAS listing: [http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm](http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm)
- SCOGRS database: [http://www.fda.gov/food/ingredientspackaginglabeling/gras/uvm2006852.htm](http://www.fda.gov/food/ingredientspackaginglabeling/gras/uvm2006852.htm)
- Drug Approvals and Database: [http://www.fda.gov/Drugs/InformationOnDrugs/default.htm](http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)
- FDA Orange Book: [https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm](https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm)
- HPVIS (EPA High-Production Volume Info Systems): [https://ofmext.epa.gov/hpvis/HPVISlogon](https://ofmext.epa.gov/hpvis/HPVISlogon)
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - [http://www.ecetoc.org](http://www.ecetoc.org)


- [www.google.com](http://www.google.com) - a general Google search should be performed for additional background information, to identify references that are available, and for other general information

**Botanical Websites, if applicable**

- GRIN (U.S. National Plant Germplasm System) - [https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx](https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx)
- National Agricultural Library NAL Catalog (AGRICOLA) [https://agricola.nal.usda.gov/](https://agricola.nal.usda.gov/)

**Fragrance Websites, if applicable**

- Research Institute for Fragrance Materials (RIFM)
DECEMBER 2019 PANEL MEETING – INITIAL REVIEW/DRAFT REPORT

Belsito Team – December 9, 2020

DR. BELSITO: So, Polysilicone-11. Just looking at the points, it's the first time we're looking at it. Is everyone happy with the method of manufacture and impurities? That's page 11.

It says, "According to a supplier, Polysilicone-11 is manufactured in cosmetic grade cyclopentasiloxane solvent, preferably from low cyclotrisiloxane, D4 feed stock using a hydrosilylation catalyst." Whatever that catalyst is.

And then the impurities, less than 20 parts per million platinum catalyst, which I guess is the catalyst for hydrosilylation. Are you happy with those?

DR. LIEBLER: I'd like to see whether there are residual monomers.

DR. BELSITO: Okay.

DR. LIEBLER: And I think that the material from industry on page 58, indicates molecular weight greater than one megadalton, very big molecules.

So, that information should be cited in the physical chemical properties section, because that makes all the difference. These are not going to be absorbed because they're huge.

DR. BELSITO: Okay. So then, that was my next question. Given size, are they insufficient for dermal absorption, and you're saying we don't need dermal absorption?

MR. LIEBLER: Don't need it.

DR. BELSITO: So, you want to add in what, from where, Dan, to show their size?

DR. LIEBLER: On Page 58, I think, there is a table or something. Let me look real quick. There is just a summary of data provided by industry, molecular weight greater than one million Dalton, i.e. one megadalton.

DR. BELSITO: And bring that into physical properties?

DR. LIEBLER: Correct. So once that's there, that pretty much nails it that these molecules are not going to be absorbed. So, we're really down to irritation and sensitization at that point. I don't know if you felt that the sensitization data were adequate?

DR. BELSITO: Yes. Because they were pretreated with SLS.

DR. LIEBLER: So, if you did then I felt like they were safe as used.

DR. BELSITO: But you just said you want to know residual monomer.

DR. SNYDER: Impurities, yeah.

DR. LIEBLER: Yeah, once the impurities. Can be addressed. I just meant that's where I see this heading.

DR. BELSITO: Okay. Well, I was going even beyond that. Okay. So basically, we need insufficient for residual monomer.

DR. LIEBLER: You know what, if these are clean, with safety data in skin tests, then we don't need to ask about residual monomers.

DR. SNYDER: Well, we do have lipstick use at 8.8 percent and sprays at 0.04 percent, so maybe we probably should have it, I think.

DR. LIEBLER: Well, if -- and if the sensitization data --

DR. BELSITO: This is the first time we're looking at it. We can ask for the data and decide later. So, insufficient for residual monomer.

DR. LIEBLER: Okay.

DR. BELSITO: Okay, now you can go to lunch. That's one way of moving through a chemical fast is to threaten holding lunch, right? Yeah, we have honey for lunch.

Marks Team – December 9, 2020

DR. MARKS: Priya, you’re up again, huh? So this is a draft report of polysiliccone-11. This is the first review of the single agent. It’s a reaction -- chemical reaction between vinyl dimethicone and hydrogen methicone, which the panel previously evaluated and found both of them to be safe. So, Ron, Tom, needs? What should we move for?
**DR. SHANK:** I have insufficient for more chemical properties. It says the test agent was a molecular weight of greater than the million, if that’s typical of the cosmetic ingredient. And I had a question -- I’m not sure what was tested -- what was mentioned was the cosmetic ingredient.

But if it isn’t molecular weight of over a million, then I don’t think it’s likely it would cross the skin. So, systemic toxicity data are not needed. But the skin sensitization data were below a maximum concentration of use. So, I thought perhaps we needed more skin sensitization data done at the maximum use concentration.

**DR. MARKS:** Yeah. So, the human maximization assay was at 25 percent, and the maximum use concentration’s up to 35 percent. So for sure, get a sensitization, preferably HRIPT at 35 percent. Yeah, even though, as you say, the molecular weight, if it is -- was that under the chemistry section of molecular weight over a million?

**DR. SHANK:** Page 58.

**DR. MARKS:** Page 58. Okay. Now, if that’s accurate, which is hard to believe, probably it’s not going to sensitize either, it’s not going to get through. But we’ll ask for that. We’ll be seconding. Tom, your input?

**DR. SLAGA:** Well, I agree with Ron, insufficient in terms of, I had that there was bacterial genotox, but there wasn’t any mammalian. I’m not sure we really need it because of the size. But it’s the first time, I wouldn’t mind seeing it.

I always love to see a 28-day dermal, just because it gives a lot of data to help support potential or give you an idea if there may be some alert for carcinogenic activity.

But once again, I don’t have any concerns. It’s nice data to have, so therefore, I’d like to see it.

**DR. MARKS:** Okay.

**DR. SHANK:** I agree, if the molecular weight’s over a million --

**DR. SLAGA:** We probably don’t need it.

**DR. SHANK:** I don’t think we need genotox or developmental, reproductive, 28-day.

**DR. ANSELL:** Or sensitization. I could see an irritation, a direct effect. But if, in fact, it’s over a million, any type of systemic driven endpoints are, I think, off the table. So, I would question whether we really do need to go up from 25 to 32 percent.

**DR. HELDRETH:** Yeah. In addition to -- if we have confidence that this is the molecular weight to expect when this ingredient was used, remember also that this ingredient is cross-linked. So, we’re not talking about a thin, linear change. We’re talking about probably a very large lattice network. So not only is there high molecular weight, there’s probably very large molecular volume.

**DR. ANSELL:** In essence, a single molecule.

**DR. SLAGA:** I don’t have any concern it’d get through to skin, but things still can have effect on the skin, right?

**DR. MARKS:** Oh, absolutely. So, the two building blocks in this were both felt to be safe. Is that reassuring? Do we need to molecular weight? Because the question would be, is the question are there smaller -- is it smaller than a molecular weight over a million? That’s what you found in your -- Priya, when you did the research, the molecular weight was defined as over a million?

**MS. CHERIAN:** It came in a data supplement.

**DR. HELDRETH:** Yeah. It was in unpublished data that was submitted to us anonymously. I mean, theoretically, you could make these polymers practically any size. They could vary from being a liquid to being a very hard rubbery material.

But the only information we have that directly points to use as an ingredient demonstrates a molecular weight this high.

**DR. MARKS:** So really, we get back to -- I guess, and then how much of the monomer would be present, and would it get through.

**DR. PETERSON:** That was my question. Whenever you have a polymer, there might be some leftovers at the beginning part.

**DR. MARKS:** So, it could be as you said, Ron Shank, to begin with, define the chemical. I guess one could also put in there as a molecular weight of a million and how much of a monomer is left. Of course, are we really worried about the monomer? I guess we really don’t know that unless we have the data.

**DR. ANSELL:** Just as a point of reference, it’s not a million, it’s in excess of a million. It’s actually not measurable.

**DR. PETERSON:** Polymers are hard to measure. Yeah. Molecular weight on it.

**DR. HELDRETH:** Particularly cross-linked.
DR. PETERSON: Yup.

DR. SHANK: So, what are you saying?

DR. ANSELL: It’s infinite. But that is a very unsatisfying answer for many people.

DR. SHANK: Yes.

DR. ANSELL: So typically, it’s just recorded as greater than a million. But it isn’t actually a million. It’s --

DR. SHANK: Really big.

DR. ANSELL: It’s really big. It’s a bounding estimate. Whatever it is, it’s certainly greater than a million.

DR. SHANK: Okay.

DR. MARKS: So tomorrow, it looks like for our team I’ll be seconding a motion. Hopefully that motion is insufficient data
\nannouncement. Lisa, the sense there is whenever we see the group of ingredients, or in this case, a single ingredient the first
\ftime, if we feel like we can’t come to a conclusion, either it’s safe or safe with whatever caveat, we’ll send out an insufficient
data announcement. And then, so by the next time we review it, industry has time -- and the CIR scientific staff have time to
get that data and then give us it.

So, it looks like we’re still back on the molecular weight and define the chemical is the real concern.

DR. SLAGA: Yeah.

DR. MARKS: And then perhaps mammalian toxicity, 28 dermal tox, and sensitization/irritation, but, Jay, I hear you loud and
\nclear. I agree with you. If it’s a large polymer, sensitization would be highly unlikely. Probably, it’s not going to be irritation.

DR. SLAGA: As well as genotoxicity. It’s highly unlikely. And we do have bacteria, which is --

DR. MARKS: So, shall we put it out tomorrow the way I stated all of this, and then see where it goes?

DR. SLAGA: See where it goes. Yeah.

DR. MARKS: And we’ll see what the Belsito team has to say.

DR. SHANK: Yes.

DR. MARKS: And oftentimes, you’ll see tomorrow, Lisa, the nice thing is, even though the two teams have the same dataset,
\nwe oftentimes will arrive at different conclusions.

DR. SHANK: Yep.

DR. MARKS: And it’s a very amiable resolution, and it’s done usually relatively quickly; with, obviously, the bottom line is
\nwhat’s safest for the public. So, we tend to be conservative. Okay. Any other comments?

DR. SHANK: On Page 11, under method of manufacture, it refers to cosmetic grade solvent. Is there such a thing as cosmetic
\ngrade? I used to use it, and I got stepped on every time. So, I’d like to ask, is there such a thing as cosmetic grade?

DR. ANSELL: No.

DR. SHANK: No. Okay.

DR. MARKS: So Priya, you’ll delete that. That’s editorial.

DR. HELDRETH: Yeah. That came directly from the anonymous submission, their verbiage.

DR. MARKS: It sounds like the evening news, the anonymous submission. I’m not so sure we can -- okay. Any other
\ncomments?

So tomorrow, presumably, I’ll be seconding an insufficient data announcement. We really want to clarify, or define, the
chemical nature of this polysilicone-11. Monomers, is the -- not is. The molecular weight is somewhere over a million it
appears. And if it’s that large a molecular weight, then we probably don’t need much more to move forward. But we discuss
the mammalian tox, the 28-day dermal tox, and sensitization and irritation. Sound good, team?

DR. SHANK: Yes.

DR. PETERSON: Yup.

DR. MARKS: Okay.

Full Panel – December 10, 2020

DR. BELSITO: Yes, so this is the first time we’re reviewing this ingredient. We thought that everything was fairly good
except we were concerned about residual monomer. And we’re going, I believe, Dan, insufficient for residual monomer.
DR. LIEBLER: Yeah, the chemistry description didn’t explicitly state how big these were, but there was a bit of data from industry on Page 58 that said that these are in excess of a million Daltons. So, I think that is going to take care of a lot of concerns for us in terms of absorption. But we typically ask for some monomer information and that’s usually available, so that’s what I think we should get here.

DR. MARKS: Yeah, our team concurs with the insufficient data announcement. Besides the molecular weight, which Priya really includes the defining the chemical monomers, we thought that we needed mammalian tox data, 28-day dermal tox, and sensitization and irritation.

We had a human maximization assay at 25 percent, but the use in a leave-on is up to 35 percent. So, we’d like to see if we could get something closer to 35 percent in that -- in this insufficient data announcement.

DR. BELSITO: Right. I mean, I’m fine with that. I just point out that the sensitization study was with pretreatment with SLS, so it was really maximizing the test. But that’s fine; as long as we’re going insufficient, we can add to the wish list.

DR. BERGFELD: So, we have a list of data needs. And, you have that list?

MS. CHERIAN: Can I get a repeat?

DR. MARKS: Yeah, the molecular weight issue and then the mammalian toxicity, 28-day dermal toxicity, and then the sensitization at use concentration at 35 percent.

DR. BELSITO: And residual monomer.

DR. MARKS: Yeah, residual -- yes, I’m sorry. Should have clarified the molecular weight.

DR. BERGFELD: Any other discussion points here or needs that the panel members think they should put in? Seeing none --

DR. GREMILLION: Can I ask?

DR. BERGFELD: Sure, Tom.

DR. GREMILLION: So, there are a couple of reports here that has this language, the inhalation language. It’s on Page 12 in this one that in practice 95 to 99 percent of the droplet particles released from cosmetic sprays have these diameters above 10 micrometers.

Is that language being refined? I couldn’t remember from our -- I know we had discussed that and there was the assertion that that was inaccurate. Was the decision made that this is sufficiently nuanced and it’s going to be in the reports here on out, or is that process ongoing to decide if this boilerplate needs to be refined?

DR. BERGFELD: Any response?

DR. HELDRETH: Yeah, we do have that finalized inhalation resource document now complete. Our plan is to start incorporating it into new reports as we move forward. But if the panel feels that we should bring that language into this report now, we certainly can do so.

DR. GREMILLION: Does it contradict this? Or is it inconsistent with this? I mean, I just remember all this conversation about -- like actually the diameter size of these sprays sometimes they’re much smaller, you know, and is this accurate?

DR. BERGFELD: Depend on the monomer. Dan?

DR. LIEBLER: I think that we considered that issue, and the problem is -- I mentioned we were talking about this yesterday. Is that even though we had additional information that we included in our inhalation tox document, that the biggest problem remains accurate assessment of particle sizes under exact conditions of use.

Even though we have a lot of new data on ways to measure particle sizes, the distributions varies quite a bit, depending on what else is in the formulation. So we felt that our existing language really didn’t change, as I recall. Gents is that -- yeah. So, in other words it’s not in conflict with what we’ve got here. But we do have a lot of additional information on the report, but it doesn’t change that part of our assessment.

DR. GREMILLION: Because this sounds like -- yeah, I mean, what you just said sounds like maybe 99 percent of the particles don’t have a diameter above this number. And these reports just keep saying, you know, the statement in practice they have these large particle sizes. It kind of, you know, throws me through a loop every time I see it. And, I’ll leave it at that.

DR. BERGFELD: Dan?

DR. LIEBLER: It’s still true.


DR. LIEBLER: I mean, it’s still true. Even though we looked at a lot more data, we ended up in the same place.
DR. GREMILLION: Okay, yeah.

DR. LIEBLER: Sorry if I wasn’t clear enough.

DR. BERGFELD: I don’t believe we called for the question on this one. I’d like to do that now. All those in favor of this conclusion of an IDA, please indicate by raising your hand. Thank you, unanimous.

Then moving on, unless there’s more discussion, here? Moving on to Honey, Dr. Marks.
Safety Assessment of Polysilicone-11 as Used in Cosmetics

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Panel Meeting Date: September 14 – 15, 2020

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Lisa A. Peterson, Ph.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Priya Cherian, Scientific Analyst/Writer, CIR.
ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of Polysilicone-11 as used in cosmetic formulations. This ingredient is reported to function as a film former. The Panel considered the available data and concluded that… [to be determined].

INTRODUCTION

This is a safety assessment of Polysilicone-11 as used in cosmetic formulations. According to the web-based International Cosmetic Ingredient Dictionary and Handbook (WINICID; Dictionary), Polysilicone-11 functions as a film former in cosmetics. Polysilicone-11 is the product of a reaction between bis-vinyldimethicone and hydrogen methicone; the Panel has previously evaluated the safety of both bis-vinyldimethicone and hydrogen methicone, and concluded that these ingredients are safe in the present practices of use and concentration in cosmetics. The full reports on these ingredients can be accessed on the Cosmetic Ingredient Review (CIR) website (https://www.cir-safety.org/ingredients).

This safety assessment includes relevant unpublished data that are available for each endpoint that is evaluated. An exhaustive search of the world’s literature was performed, and very little published data were found regarding this ingredient. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints the Panel typically evaluates, is provided on the CIR website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

CHEMISTRY

Definition and Structure

According to the Dictionary, Polysilicone-11 (CAS No: 63394-02-5, 156065-02-0) is a crosslinked dimethyl siloxane formed by the reaction of bis-vinyldimethicone and hydrogen dimethicone.

Figure 1. Polysilicone-11 reactants (wherein each instance of R may be hydrogen or methyl; x, y, and z not defined)

For use in cosmetics, copolymers, such as Polysilicone-11, are typically supplied to finishing houses as swollen gels (i.e. trade name mixtures) that contain 1 or more solvents (e.g., cyclopentasiloxane). The addition of the comonomer (i.e. the vinyl-substituted dimethicone) affects both the chemical and the rheological properties of the resultant ingredient. Furthermore, the degree of crosslinking could also significantly affect these properties. Accordingly, this copolymer ingredient theoretically represents a wide variety of materials ranging from liquids to elastomeric solids.

Chemical Properties

While no material properties were found or submitted for this ingredient alone, specifications for tradename mixtures comprising, in part, Polysilicone-11 were found. For 3 different tradename mixtures, Polysilicone-11 was stated to comprise 10 – 20% of the mixture composition. The composition remainder of these mixtures (i.e. the other 80 – 90%) was reported to be isododecane, cyclopentasiloxane, or dimethicone. Each of these tradename mixtures is a clear liquid, with a viscosity ranging from 300 to 500 pascal second (Pa·s). The molecular weight of Polysilicone-11 has been reported to be greater than 1 million Da, in the form of an elastomer rubber, amorphous polymer.

Method of Manufacture

According to a supplier, Polysilicone-11 is manufactured in cyclopentasiloxane (D5) solvent, preferable from low cyclotetrasiloxane (D4) feedstock using a hydrosilation catalyst. This is reported to be a pure addition reaction in which no impurities are formed during the reaction and no residual monomers remain after completion.

Impurities

According to a manufacturer, Polysilicone-11 generally contains less than 20 ppm platinum catalyst from hydrosilation. The same manufacturer also reported that heavy metal testing results for Polysilicone-11 typically include: below limits of detection for mercury, and less than 1 ppm for lead and arsenic.
USE

Cosmetic

The safety of the cosmetic ingredient addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in the FDA Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by the cosmetic industry in response to a survey, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

According to the 2020 VCRP survey data, Polysilicone-11 is reported to be used in 440 total formulations (432 of which are leave-on formulations; Table 1). The majority of these uses are in face and neck (excluding shave) products, moisturizing products, eye lotions, and foundations. The results of the concentration of use survey conducted by the Council in 2018, and updated in 2019, indicate Polysilicone-11 is used at up to 19.9% in products that have dermal exposure (i.e., other skin care preparations). This ingredient may result in incidental ingestion as it is reported to be used in 8 lipstick formulations at up to 8.8%. In addition, Polysilicone-11 may also be used near the eyes, as it is reported to be used in eyeliner (1 formulation; concentration of use not reported), eye shadows (30 formulations; up to 9.4%), eye lotions (46 formulations; up to 12.2%), mascaras (3 formulations; up to 0.59%), and other eye makeup preparations (19 formulations; up to 0.24%).

Additionally, Polysilicone-11 is used in cosmetic sprays and could possibly be inhaled; for example, it is reported to be used in suntan pump sprays at up to 0.04%. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters > 10 µm, with propellant sprays yielding a greater fraction of droplets/particles < 10 µm compared with pump sprays. Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount. Polysilicone-11 was reportedly used in face powders at concentrations up to 3.5%, and could possibly be inhaled. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the air.

Polysilicone-11 is not restricted from use in any way under the rules governing cosmetic products in the European Union.

TOXICOKINETIC STUDIES

Toxicokinetics studies were not found in the published literature, and unpublished data were not submitted.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

An acute oral toxicity study was performed on Sprague Dawley rats (5/sex) using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane. The test substance was administered undiluted. The LD50 was reported to be > 5 g/kg. No other details regarding this study were provided.

Short-Term, Subchronic, and Chronic Toxicity

Short-term, subchronic, and chronic toxicity studies on Polysilicone-11 were neither found in the published literature, nor were these data submitted.

GENOTOXICITY

The genotoxic potential of a mixture consisting of 14% Polysilicone-11, 47% dimethicone, and 39% cyclopentasiloxane, was evaluated in an Ames assay. Bacterial cell lines (Salmonella typhimurium strains TA98 and TA100) were tested with and without metabolic activation. The test substance was tested at concentrations of 50, 100, 500, 1000, and 5000 µg/plate, and was considered to be non-mutagenic.

CARCINOGENICITY STUDIES

Data on the carcinogenicity of Polysilicone-11 were neither found in the published literature, nor were these data submitted.

OTHER RELEVANT STUDIES

Cytotoxicity

An agar diffusion test was performed in vitro to determine the biological reactivity of a mammalian cell culture (not specified) following indirect contact with the test substance (a trade name mixture containing 12 - 16% Polysilicone-11, 43 -
50% dimethicone, and 36 - 42% cyclpentasiloxane). The test substance exhibited no reactivity after the 24-hour observation period, and did not induce cytotoxicity.

**DERMAL IRRITATION AND SENSITIZATION**

Details of the dermal irritation and sensitization studies summarized below are provided in Table 2.

**Irritation**

A skin irritation study was performed on 6 New Zealand white albino rabbits. The test substance (6% Polysilicone-11 and 94% cyclotetrasiloxane) was applied, undiluted, under a patch (type of patch not specified), on intact and abraded skin. The test substance was not considered to be a primary irritant. A 48-h patch test was performed on 50 subjects using a lipstick containing 1.8% Polysilicone-11 under semi-occlusive conditions. No dermal irritation was observed. Similarly, a 7-d dermal irritation study was performed on 38 subjects using a face cream containing 1.6% Polysilicone-11 under semi-occlusive conditions. On day 1, patches were applied for 24 h and removed. After evaluation of the site, identical patches were applied to the same site, and the process was repeated for 7 d. The subjects showed no evidence of irritation to the test substance.

**Sensitization**

A human repeated insult patch test (HRIPT) was performed to evaluate the sensitization potential of a product containing 1.45% Polysilicone-11. The test article was placed on the skin of 54 subjects, under an occlusive patch. No evidence of irritation or sensitization was observed. No sensitization was observed in an HRIPT performed on 51 subjects using a facial product containing 9.68% Polysilicone-11. The test substance was applied neat, under semi-occlusive conditions. An HRIPT was performed on 50 subjects using a test substance consisting of 11% Polysilicone-11 and 89% cyclpentasiloxane. All applications were performed neat (type of patch used not specified). The test substance was considered to be non-irritating and non-sensitizing. Another HRIPT was performed, according to the same procedure, on 110 subjects using a facial product containing 19.83% Polysilicone-11. Applications were made using a 10% dilution of the test substance (2% Polysilicone-11) under a semi-occlusive patch. No sensitization was observed. The amount of test substance used was not stated in either study. A maximization assay was performed on 17 subjects to evaluate the sensitization potential of a test substance containing 24.625% Polysilicone-11 (applied undiluted). No instances of contact allergy were recorded at either 48 or 72 h after the application of the challenge patch. The test substance was not considered to possess a detectable contact-sensitizing potential. No signs of sensitization were observed when an HRIPT was performed on 51 subjects using a trade name mixture consisting of 98% Polysilicone-11 and 2% laureth-12.

**OCULAR IRRITATION STUDIES**

**In Vitro**

A tissue equivalent assay was performed with EpiOcular™ cultures to evaluate the ocular irritation potential of a face cream containing 1.6% Polysilicone-11. The face cream was tested neat (100 µl), the test samples were treated in duplicate, and the exposure periods were 8, 16, 20, and 24 h. Appropriate negative and positive controls were used. The ET50s (i.e., the time at which the tissue viability was reduced 50% compared to negative control tissues) for Polysilicone-11 and the positive control were 18.2 h and 30.3 min, respectively.

A MatTek EpiOcular™ methyl thiazole tetrazolium (MTT) viability assay was also performed to evaluate the ocular irritation potential of a test substance containing 98.5% Polysilicone-11. The chemical was tested neat (100 µl), the test samples were treated in duplicate, and the exposure periods were 64, 256, and 1200 min. Appropriate negative and positive controls were used. The ET50 was 12 h, and the ocular irritancy classification for this test substance was “non-irritating, minimal.”

**Animal**

An acute eye irritation study was performed on 6 New Zealand albino rabbits using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane. Approximately 0.1 ml of the test substance was applied to the eye, undiluted. No other details regarding this study were provided. The test substance was reported to be minimally irritating.

**SUMMARY**

This is a safety assessment of Polysilicone-11 as used in cosmetics. According to the Dictionary, Polysilicone-11 is a crosslinked dimethyl siloxane formed by the reaction of bis-vinylidimethicone and hydrogen dimethicone, and is reported to function as a film former in cosmetics.

According to 2020 VCRP data, Polysilicone-11 is reported to be used in 440 formulations, 432 of which are leave-on formulations. The majority of these uses are in face and neck (excluding shave) products, moisturizing products, eye lotions, and foundations. Results of the concentration of use survey conducted by Council in 2018, and updated in 2019, indicate Polysilicone-11 is used at a maximum concentration of up to 19.9% in other skin care preparations.

An LD<sub>50</sub> of > 5 g/kg was established in an acute oral toxicity study performed on Sprague-Dawley rats given a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane.
No mutagenicity was reported in an Ames assay performed using a mixture consisting of 14% Polysilicone-11, 47% dimethicone, and 39% cyclopentasiloxane. The test substance was tested on *S. typhimurium* (TA98 and TA100) at concentrations of up to 5000 µg/plate.

No cytotoxicity was observed in an agar diffusion test using a test substance consisting of 12 - 16% Polysilicone-11, 43 - 50% dimethicone, and 36 - 42% cyclopentasiloxane.

No irritation was observed in a skin irritation study performed on New Zealand white albino rabbits using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane. A 48-h patch test was performed on 50 subjects using a lipstick containing 1.8% Polysilicone-11. No irritation was observed. In addition, no dermal irritation was observed in a 7-d dermal irritation study (24-h patches) performed on 38 subjects using a face cream containing 1.6% Polysilicone-11.

No sensitization was observed in multiple HRIPTs using the following test materials: a facial product containing 9.68% Polysilicone-11, a 10% dilution of a facial product containing 19.83% Polysilicone-11 (2% Polysilicone-11 as actual test concentration), a mixture of 11% Polysilicone-11 and 89% cyclopentasiloxane, a product containing 1.45% Polysilicone-11, or a trade name mixture containing 98% Polysilicone-11 and 2% laureth-12. In a maximization assay performed on 27 subjects using a pre-treatment with SLS, the test substance (containing 24.625% Polysilicone-11) was considered to be non-sensitizing.

An in vitro tissue equivalent assay was performed in order to evaluate the ocular irritation potential of a face cream containing 1.6% Polysilicone-11. The ET50s for Polysilicone-11 and the positive control were 18.2 h and 30.3 min, respectively. A MatTek EpiOcular™ MTT viability assay was also performed to evaluate the ocular irritation potential of a test substance containing 98.5% Polysilicone-11. The ET50 was 12 h, and the ocular irritancy classification for this test substance was “non-irritating, minimal.” In an ocular irritation study in New Zealand white rabbits, a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane applied to the eyes was considered to be minimally irritating.

**DRAFT DISCUSSION**

*Please note, this discussion is in draft form and will be modified following the meeting.*

The Panel discussed the issue of incidental inhalation exposure from powders and suntan pump sprays. The Council survey results indicate that Polysilicone-11 is being used in face powders at concentrations up to 3.5%. In addition, Polysilicone-11 is used in spray suntan products at up to 0.04%. The Panel noted that in aerosol products, 95% – 99% of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel’s approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at [https://www.cir-safety.org/cir-findings](https://www.cir-safety.org/cir-findings).

**CONCLUSION**

To be determined.
# Table 1. Frequency and concentration of use of Polysilicone-11

<table>
<thead>
<tr>
<th>Exposure Type</th>
<th># of Uses</th>
<th>Max Conc. of Use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Totals</strong></td>
<td>440</td>
<td>0.025 – 19.9</td>
</tr>
<tr>
<td><strong>Duration of Use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leave-On</td>
<td>412</td>
<td>0.025 – 19.9</td>
</tr>
<tr>
<td>Rinse-Off</td>
<td>8</td>
<td>0.061 – 5.8</td>
</tr>
<tr>
<td>Diluted for (Bath) Use</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td><strong>Eye Area</strong></td>
<td>94</td>
<td>0.24 – 12.2</td>
</tr>
<tr>
<td>Incidental Ingestion</td>
<td>8</td>
<td>7.2 – 8.8</td>
</tr>
<tr>
<td>Incidental Inhalation-Spray</td>
<td>100(^a), 90(^b)</td>
<td>0.04; 0.47 – 0.48 (^b)</td>
</tr>
<tr>
<td>Incidental Inhalation-Powder</td>
<td>8, 100(^a)</td>
<td>0.025 – 3.5; 0.08 – 14.6 (^c)</td>
</tr>
<tr>
<td>Dermal Contact</td>
<td>407</td>
<td>0.025 – 19.9</td>
</tr>
<tr>
<td>Deodorant (underarm)</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Hair - Non-Coloring</td>
<td>1</td>
<td>0.48</td>
</tr>
<tr>
<td>Hair-Coloring</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Nail</td>
<td>1</td>
<td>NR</td>
</tr>
<tr>
<td>Mucous Membrane</td>
<td>8</td>
<td>7.2 – 8.8</td>
</tr>
<tr>
<td>Baby Products</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

\(^a\) Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.  
\(^b\) Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories  
\(^c\) It is possible these products are powders, but it is not specified whether the reported uses are powders  
NR – no reported use
<table>
<thead>
<tr>
<th>Test Article</th>
<th>Concentration/Dose</th>
<th>Test Population</th>
<th>Procedure</th>
<th>Results</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANIMAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6% Polysilicone-11 and 94% cyclotetrasiloxane</td>
<td>100%; 0.5 g</td>
<td>6 New Zealand White Rabbits</td>
<td>The test substance was applied under a 2.5 cm² patch on intact and abraded skin (type of patch not specified)</td>
<td>Non-irritating</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HUMAN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product containing 1.45 % Polysilicone-11</td>
<td>100%; 0.1 – 0.15 g</td>
<td>54</td>
<td>HRIPT; The test substance was applied neat, under an occlusive patch, 3 times per week during the induction period. The amount of test substance used was not reported. Patches were removed 24 h after each application. After a 2-wk rest period, a challenge patch was applied to a previously untreated test site. Patches were removed and the site was scored 24 and 72 h post-application.</td>
<td>Non-irritating; Non-sensitizing</td>
<td>22</td>
</tr>
<tr>
<td>Lipstick containing 1.8% Polysilicone-11</td>
<td>100%; 0.2 ml</td>
<td>50</td>
<td>The test material was applied to a 1” x 1” absorbent pad portion of a clear adhesive dressing, and placed on the back. This dressing formed a semi-occlusive patch. The material remained on the skin for 2 d.</td>
<td>Non-irritating</td>
<td>20</td>
</tr>
<tr>
<td>Face cream containing 1.6% Polysilicone-11</td>
<td>100%; 0.2 g</td>
<td>38</td>
<td>On day 1, the undiluted test substance (0.2 g) was applied to the back, under semi-occlusive conditions. After approximately 24 h, patches were removed. Twenty to 40 minutes after patch removal, sites were evaluated, and identical patches were applied to the same site. This process was repeated daily for a total of 7 d. Distilled water and 0.75% sodium lauryl sulfate (SLS) served as the negative and positive controls, respectively.</td>
<td>Non-irritating</td>
<td>21</td>
</tr>
<tr>
<td>Facial product containing 9.68% Polysilicone-11</td>
<td>100%; amount of test substance not reported</td>
<td>51</td>
<td>HRIPT (same procedure as above); semi-occlusive patch</td>
<td>Non-sensitizing</td>
<td>23</td>
</tr>
<tr>
<td>11% Polysilicone-11 and 89% cyclopentasiloxane</td>
<td>100%; amount of test substance not reported</td>
<td>50</td>
<td>HRIPT (same procedure as above); patch type not specified</td>
<td>Non-irritating; Non-sensitizing</td>
<td>19</td>
</tr>
<tr>
<td>Facial product containing 19.83% Polysilicone-11</td>
<td>100%; 10% dilution (actual test concentration 2% Polysilicone-11); amount of test substance not reported</td>
<td>110</td>
<td>HRIPT (same procedure as above); semi-occlusive patch</td>
<td>Non-sensitizing</td>
<td>23</td>
</tr>
<tr>
<td>Liquid blend containing 24.625% Polysilicone-11</td>
<td>100%; 0.05 ml</td>
<td>17</td>
<td>Maximization assay. Approximately 0.05 ml of aqueous SLS was applied to the skin of each subject under occlusive conditions for 24 h. After 24 h, patches were removed and 0.05 ml of the test material was applied to the same site, and covered with occlusive tape. This induction patch was left in place for 48 or 72 h. After removal of the induction patches, if no irritation was present, a 0.25% SLS aqueous patch was again reapplied to the same site for 24 h, followed by reapplication of a fresh induction patch with the test material. This sequence of SLS pre-treatment followed by 48 h of test material application continued for a total of 5 induction exposures. The induction phase was followed by a 10-d rest period. After the rest period, subjects were challenged with a single, 48-h application of the test material to a previously untreated site. Pre-treatment with SLS was performed prior to challenge. Evaluations were performed 48 and 72 h after application of challenge patch.</td>
<td>Non-sensitizing</td>
<td>24</td>
</tr>
<tr>
<td>Trade name mixture containing 98% Polysilicone-11 and 2% laureth-12</td>
<td>100%; 0.2 g</td>
<td>51</td>
<td>HRIPT (same procedure as above); occlusive patch</td>
<td>Non-irritating; Non-sensitizing</td>
<td>25</td>
</tr>
</tbody>
</table>

HRIPT = human repeated insult patch test; SLS = sodium lauryl sulfate
REFERENCES


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   Personal Care Products Council on December 18, 2019.)

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   College Park, MD.

    data submitted to Personal Care Products Council on December 18, 2019.)


    CIR Expert Panel meeting. Washington, D.C.

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# 2020 VCRP Data – Polysilicone-11

<table>
<thead>
<tr>
<th>Product Description</th>
<th>% of Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyeliner</td>
<td>1</td>
</tr>
<tr>
<td>Eye Shadow</td>
<td>30</td>
</tr>
<tr>
<td>Eye Lotion</td>
<td>46</td>
</tr>
<tr>
<td>Mascara</td>
<td>3</td>
</tr>
<tr>
<td>Other Eye Makeup Preparations</td>
<td>19</td>
</tr>
<tr>
<td>Powders (dusting and talcum, excluding aftershave talc)</td>
<td>2</td>
</tr>
<tr>
<td>Tonics, Dressings, and Other Hair Grooming Aids</td>
<td>1</td>
</tr>
<tr>
<td>Blushers (all types)</td>
<td>3</td>
</tr>
<tr>
<td>Face Powders</td>
<td>6</td>
</tr>
<tr>
<td>Foundations</td>
<td>43</td>
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<tr>
<td>Leg and Body Paints</td>
<td>1</td>
</tr>
<tr>
<td>Lipstick</td>
<td>11</td>
</tr>
<tr>
<td>Makeup Bases</td>
<td>12</td>
</tr>
<tr>
<td>Rouges</td>
<td>2</td>
</tr>
<tr>
<td>Other Makeup Preparations</td>
<td>20</td>
</tr>
<tr>
<td>Other Manicuring Preparations</td>
<td>1</td>
</tr>
<tr>
<td>Aftershave Lotion</td>
<td>1</td>
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<tr>
<td>Cleansing</td>
<td>4</td>
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<tr>
<td>Face and Neck (exc shave)</td>
<td>78</td>
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<tr>
<td>Body and Hand (exc shave)</td>
<td>23</td>
</tr>
<tr>
<td>Foot Powders and Sprays</td>
<td>1</td>
</tr>
<tr>
<td>Moisturizing</td>
<td>63</td>
</tr>
<tr>
<td>Night</td>
<td>23</td>
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<tr>
<td>Paste Masks (mud packs)</td>
<td>4</td>
</tr>
<tr>
<td>Skin Fresheners</td>
<td>1</td>
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<tr>
<td>Other Skin Care Preps</td>
<td>35</td>
</tr>
<tr>
<td>Indoor Tanning Preparations</td>
<td>6</td>
</tr>
</tbody>
</table>
Memorandum

TO: Bart Heldreth, Ph.D.
   Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Carol Eisenmann, Ph.D.
       Personal Care Products Council

DATE: December 18, 2019

SUBJECT: Polysilicone-11


AMA Laboratories, Inc. 2016. Agar diffusion cytotoxicity test (ISO method) GRANSIL
   DMDM-5 (43-50% Dimethicone; 36-42% Cyclopentasiloxane; 12-16% Polysilicone-11).
August 2019
Clarifications Added December 18, 2019

Method of Manufacture and Impurities: Polysilicone-11
From Grant Industries, Inc.

Polysilicone-11 (Cyclosiloxanes, dimethyl, polymers with dimethyl, methyl hydrogen siloxanes and vinyl-group terminated dimethylsiloxanes) is manufactured in cosmetic grade D5 (cyclopentasiloxane) solvent, preferable from low D4 (cyclotetrasiloxane) feedstock using a hydrosilation catalyst. It is a very pure addition reaction, with no impurities being formed during the reaction.

By virtue of additions, the product contains generally <20 ppm platinum catalyst from hydrosilation.

Molecular Weight: >1 million Daltons in the form of an elastomer rubber, amorphous polymer

There are no residual monomers. Polysilicone-11 is formed by linking the two polymers together via hydrosilation with a platinum catalyst. There are no fractions under 1500 Daltons, as the starting polymers are generally greater than 1500 Daltons.

There are no impurities beyond what has already been disclosed. Heavy metal testing is typically non-detectable for mercury, with lead and arsenic <1 ppm.
AGAR DIFFUSION CYTOxicITY TEST (ISO METHOD)

AMA Ref. No.: MS06.CYTOTOX.K9633.GII

DATE: 12/14/06

SPONSOR: Grant Industries, Inc.
103 Main Avenue
Elmwood Park, New Jersey 07407-3203

PURPOSE OF THE STUDY:
The Agar Diffusion Test is an in vitro procedure designed to determine the biological reactivity of mammalian cell cultures following indirect contact with the test material that has been provided by Grant Industries and labeled as follows:

AMA Lab No.: K-9633

Client No.: GRANSIL DMCM-5 Lot No.1005316

TEST CRITERIA: The cell culture test system is suitable if the observed responses to the negative control is a grade 0 (no reactivity) and to the positive control is at least a grade 3 (moderate reactivity). The test article meets the requirements of the test if the response to the test article is not greater than grade 2 (mildly reactive). The test must be repeated if the suitability of the test system is not confirmed. If there are evident differences in the test result for replicate culture vessels, then the test is either inappropriate or invalid.
RESULTS:
Results are presented in Table 1 of this report. Suitability of the test system was confirmed. The test results were consistent among all replicates.

SUMMARY/CONCLUSION:
The test article: K-9633 exhibited no reactivity (Grade 0) after the 24 hour observation point and did not induce cytotoxicity. The test article K-9633 (GRANSIL DMCM-5, Lot No. 1005316) does meet the criteria of the test since no reactivity was observed.

Respectfully submitted,

David R. Winne
Technical Director
AMA Laboratories, Inc.
Results

Agar Diffusion Cytotoxicity Test
(ISO Method)

Test Article: K-9633
GRANSIL DMCM-5 Lot No. 1005316

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<th>Sample Description</th>
<th>Sample Identification</th>
<th>Grade (Plates 1,2,3)</th>
<th>Reactivity</th>
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## EXPLANATION OF BIOLOGICAL REACTIVITY

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Memorandum

TO: Bart Heldreth, Ph.D.
   Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Carol Eisenmann, Ph.D.
       Personal Care Products Council

DATE: March 9, 2020

SUBJECT: Polysilicone-11

Grant Industries, Inc. 2020. Summary of an HRIPT on Grasil LS a trade name mixture containing 98% Polysilicone-11 and 2% Laureth-12.
Summary of an HRIPT on Gransil EP-LS a Trade Name Mixture Containing 98% Polysilicone-11 and 2% Laureth-12

Grant Industries, Inc. 2020

The study was completed in 2007 by AMA Laboratories.

Test material: 98% polysilicone-11 + 2% Laureth-12 (This is a solid Polysilicone-11 powder where the silicone solvent has been stripped off and some Laureth-12 added as a flow aid)

A total of 51 subjects (21 men; 30 women) enrolled in the study; all subjects completed the study.

0.2 g of the test material was placed on the occlusive, hypoallergenic patch

The patch was applied to the skin of the infrascapular region of the back

Subjects removed the patches after 24 hours.

This procedure was repeated for a total of nine 24-hour exposure every Monday, Wednesday and Friday for 3 weeks

Subjects were given a 10 to 14 day rest period after a challenge dose was applied to a previously unexposed test site. Reactions were scored 24 and 48 hours after application.

No adverse reactions of any kind were noted during the course of the study.

The test material when tested under occlusion, may be considered as a non-primary irritant and non-primary sensitizer.
# TABLE
SUMMARY OF RESULTS
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Client No.: Gransil EP-LS, Lot No.: 1250908015

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### TABLE (CONT'D)
#### SUMMARY OF RESULTS
( Occlusive Patch)

**AMA Lab No.:** L-0621  
**Client No.:** Gransil EP-LS, Lot No.: 1250908015

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</tr>
</tbody>
</table>

**Evaluation Period:**

This study was conducted from April 27, 2007 through May 30, 2007.
### Concentration of Use by FDA Product Category – Polysilicone-11

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Maximum Concentration of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye shadows</td>
<td>2.3-9.4%</td>
</tr>
<tr>
<td>Eye lotions</td>
<td>1.5-12.2%</td>
</tr>
<tr>
<td>Mascaras</td>
<td>0.59%</td>
</tr>
<tr>
<td>Other eye makeup preparations</td>
<td>0.24%</td>
</tr>
<tr>
<td>Tonics, dressings and other hair grooming aids</td>
<td>0.48%</td>
</tr>
<tr>
<td>Blushers</td>
<td>2.4-4.9%</td>
</tr>
<tr>
<td>Face powders</td>
<td>0.025-3.5%</td>
</tr>
<tr>
<td>Foundations</td>
<td>0.48-14.4%</td>
</tr>
<tr>
<td>Lipstick</td>
<td>7.2-8.8%</td>
</tr>
<tr>
<td>Makeup bases</td>
<td>0.65-0.73%</td>
</tr>
<tr>
<td>Makeup fixatives</td>
<td>1.8%</td>
</tr>
<tr>
<td>Aftershave lotions</td>
<td>1.4%</td>
</tr>
<tr>
<td>Skin cleansing (cold creams, cleansing lotions, liquids and pads)</td>
<td>0.061-1.1%</td>
</tr>
<tr>
<td>Face and neck products</td>
<td></td>
</tr>
<tr>
<td>Not spray</td>
<td>0.08-14.6%</td>
</tr>
<tr>
<td>Body and hand products</td>
<td></td>
</tr>
<tr>
<td>Not spray</td>
<td>2.5-12.5%</td>
</tr>
<tr>
<td>Moisturizing products</td>
<td></td>
</tr>
<tr>
<td>Not spray</td>
<td>0.25-1.5%</td>
</tr>
<tr>
<td>Paste masks and mud packs</td>
<td>5.8%</td>
</tr>
<tr>
<td>Other skin care preparations</td>
<td>6.8-19.9%</td>
</tr>
<tr>
<td>Suntan products</td>
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</tr>
<tr>
<td>Not spray</td>
<td>0.35%</td>
</tr>
<tr>
<td>Pump spray</td>
<td>0.04%</td>
</tr>
<tr>
<td>Indoor tanning preparations</td>
<td>0.47%</td>
</tr>
</tbody>
</table>

Information collected in 2018
Table prepared June 26, 2018
Corrected December 18, 2019: 35% high concentration for Face and Neck products changed to 14.6%